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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,514	09/22/2003	Marius Hauri	0100/0165	5820
21395	7590	11/01/2005	EXAMINER HAYES, MICHAEL J	
LOUIS WOO LAW OFFICE OF LOUIS WOO 717 NORTH FAYETTE STREET ALEXANDRIA, VA 22314			ART UNIT 3767	PAPER NUMBER

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/665,514

Applicant(s)

HAURI ET AL.

Examiner

Michael J. Hayes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 September 2003.  
2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-5, 7-24 and 26-28 is/are rejected.  
7) ☒ Claim(s) 6 and 25 is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 22 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 9/22/03.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 recites the limitation "said safety device" in line 6. There is insufficient antecedent basis for this limitation in the claim.

### *Specification*

The abstract of the disclosure is objected to because it is longer than 150 words. Correction is required. See MPEP § 608.01(b).

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 7, 20-22, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by GYURE et al. (US Patent No. 5,681,295). Gyure discloses a safety apparatus including a needle hub, collar rotatably mounted, housing pivotally connected to the collar, needle sheath 37,

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engage mechanisms (40 and proximal portion, hub distal portion) on the sheath and collar respectively, needle hub with flange and wall 33, 32, collar protrusion 43. The method of making the assembly is inherent in the disclosure of the finished assembly of component parts.

*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over GYURE as applied claims 1 and 20 and further in view of LANDIS (US Patent No. 5,490,841). Gyure discloses the claimed invention except for the overlapping housing lips with off-centered opening. Landis teaches the use of overlapping housing lips with off-centered opening. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Landis in the apparatus and method of Gyure in order to easily entrap the needle with the housing.

Claims 9, 10, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over GYURE as applied to claims 1 and 20 above, and further in view of GYURE (US Patent No. 5,669,889). Gyure '295 discloses the claimed invention except for lock mechanisms on the collar and housing to matingly couple to retain the housing to the collar. Gyure '889 teaches lock mechanisms on the collar and housing to matingly couple to retain the housing to the collar (61, 57, fig. 3). It would have been obvious to one of ordinary skill in the art at the time of the

invention to use the teachings of Gyure '889 in the apparatus and method of Gyure '295 in order to prevent the housing from re-exposing the needle after covering.

Claims 4 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over GYURE as applied to claims 1 and 20 above, and further in view of CRAWFORD. Gyure discloses the claimed invention except for a groove on the needle sheath to mate with a circumferential rib on the collar inner wall. Crawford teaches a groove and rib combination to secure a sheath to a collar. See fig. 2, 97 on collar and groove between elements 56 on sheath 50. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Crawford in the apparatus and invention of Gyure in order to provide a secure fit between the sheath and collar.

Claims 5, 11, 12, 13, 16, 17, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over GYURE '295 as applied to claims 1 and 20 above, and further in view of Johnson (US Pub. No. 2002/0010433). Gyure '295 discloses the claimed invention as discussed above including a needle hub with luer end to connect to the luer end of the barrel (4:62-5:17). Gyure does not disclose a ring spaced around the hub end for a user to grasp. Johnson teaches a ring spaced around a hub end for a user to grasp (figs. 2a-e). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Johnson in the apparatus and method of Gyure in order to facilitate connection of the hub and barrel.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over GYURE '295 and Johnson as applied to claim 12 above, and further in view of CRAWFORD (US Pub. No. 20020161336). Gyure and Johnson disclose the claimed invention except for a groove on the needle sheath to mate with a circumferential rib on the collar inner wall. Crawford teaches a

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groove and rib combination to secure a sheath to a collar. See fig. 2, 97 on collar and groove between elements 56 on sheath 50. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Crawford in the apparatus and invention of Gyure and Johnson in order to provide a secure fit between the sheath and collar.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over GYURE and JOHNSON as applied to claim 11 and further in view of LANDIS. Gyure and Johnson disclose the claimed invention except for the overlapping housing lips with off-centered opening. Landis teaches the use of overlapping housing lips with off-centered opening. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Landis in the apparatus and method of Gyure and Johnson in order to easily entrap the needle with the housing.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over GYURE and JOHNSON as applied to claim 11 above, and further in view of GYURE (US Patent No. 5,669,889). Gyure '295 and Johnson disclose the claimed invention except for lock mechanisms on the collar and housing to matingly couple to retain the housing to the collar. Gyure '889 teaches lock mechanisms on the collar and housing to matingly couple to retain the housing to the collar (61, 57, fig. 3). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Gyure '889 in the apparatus and method of Gyure '295 and Johnson in order to prevent the housing from re-exposing the needle after covering.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

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improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 20, 21, 22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 5, 9, 10, 17, 23, and 24 of copending Application No. 10/2649837. Although the conflicting claims are not identical, they are not patentably distinct from each other because they each recite a needle hub, collar, pivotable housing, and needle sheath.

Claims 1, 2, 20, 21, 22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 7, 8, 11, 20, of copending Application No. 10/2649837. Although the conflicting claims are not identical, they are not patentably distinct from each other because they each recite a needle hub, collar, pivotable housing, and needle sheath.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

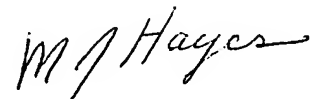
*Allowable Subject Matter*

Claims 6 and 25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (571) 272-4959. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons, can be contacted at (571) 272-4965. The fax number for submitting official papers is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mjh  
28 October 2005



**MICHAEL J. HAYES**  
**PRIMARY EXAMINER**